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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

Proceeding	91178825
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IN THE UNITED STATES PATENT AND TRADEMARK OFFICE
BEFORE THE TRADEMARK TRIAL AND APPEAL BOARD

RISING PHARMACEUTICALS, INC., Opposer, -against- PEDINOL PHARMACEUTICAL, INC., Applicant.	Opposition No. 91178825 Serial No. 77/0690983

MEMORANDUM OF LAW FOR RISING PHARMACEUTICALS, INC. IN OPPOSITION TO APPLICANT'S PARTIAL MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED

Rising Pharmaceuticals, Inc. ("Opposer") respectfully submits this Memorandum of Law in opposition to the "partial motion to dismiss" for failure to state a claim filed by Applicant, Pedinol Pharmaceuticals, Inc. ("Applicant"). Applicant's partial motion to dismiss is without merit and should be denied.

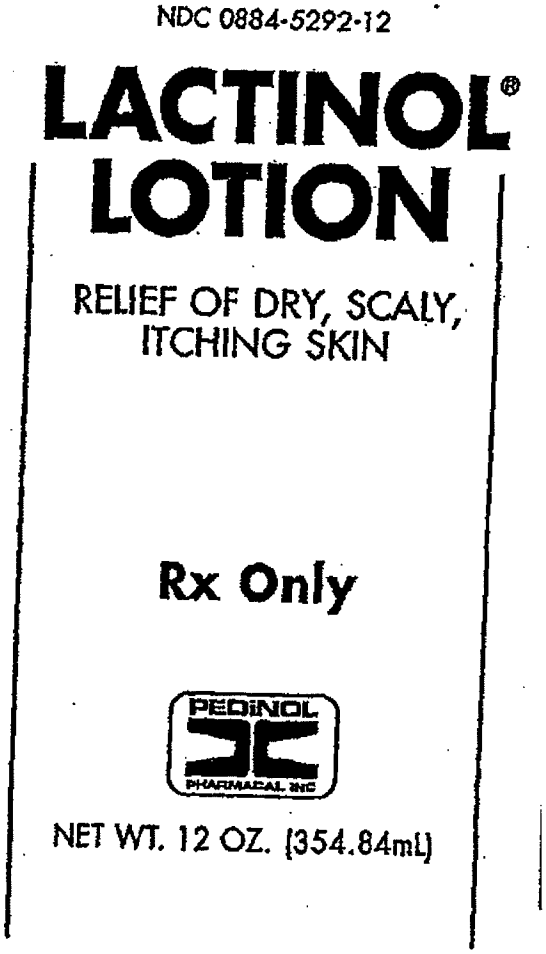
I: Summary

BACKGROUND OF THE PROCEEDING

On December 11, 2006, Applicant submitted its Application under Section 1(a) for registration of the word mark LACTINOL in International Class 005. The Application claims a first use at least as early as June 17, 1992 for goods described as " Medicated lotions for use in treatment of dry, scaly, itching skin". The submitted specimen label – different form the one in which it has historically utilized -- shows a product intrinsically identified only as "Lactinol Lotion" on the principal display panel and designating the claimed use as "Rx Only." Applicant

thus concedes that its claimed section 1(a) use is of a product subject to regulation by the United States Food and Drug Administration ("FDA") as a prescription drug under the United States Food Drug & Cosmetic Act, 21 USC 301, *et seq.(*"FFDCA").

After Applicant's mark was published for opposition, Opposer Rising Pharmaceuticals Inc. commenced this proceeding by its Notice of Opposition dated August 8, 2007. Opposer succinctly alleges that it is a direct competitor of Applicant in sale of lactic acid 10% drug products and explains that it would be injured if the proposed mark would be registered. Rising's Notice of Opposition ("OPP") further sets forth that Applicant is not entitled to registration because, as exemplified by the following specimen, Applicant's claimed use is unlawful in three material respects as follows:



SALE WITHOUT FDA APPROVAL

Applicant's use of the LACTINOL mark, alleged to have been since June 17, 1992, has been predicated on unlawful use in commerce in violation of the United States Food Drug and Cosmetic Act , 21 U.S.C. §355(a), *et seq.*, and the regulations and guidance promulgated thereunder, which require prescription drug products to be pre-approved by the FDA prior to marketing. (OPP paragraph 4)

Applicant has not sought or obtained such FDA approval for its Lactic acid 10 % product and its use of the LACTINOL name in connection therewith is therefore predicated on unlawful commerce. (OPP paragraph 5)

Registration of the LACTINOL mark by Applicant would likely result in purchasers and prospective purchasers being misled into believing that Applicant's prescription drug product is approved for use by the FDA, when in fact it has no such approval. (OPP paragraph 6)

Opposer would be injured by the granting to Applicant of a Certificate of Registration for the mark LACTINOL because Applicant would be granted exclusive rights in such mark based on unlawful use, in violation of the Trademark Act, Title 15 U.S.C., and the grant of such registration would provide Applicant with the unfair benefits of the imprimatur of approval of a "brand name" in order to represent and imply, and thereby confuse Opposer's customers, potential customers and the market in general, into mistakenly believing that Applicant's prescription lactic acid 10% drug products are FDA-approved branded items. (OPP paragraph 7)

SALE WITH ILLEGAL LABEL

Applicant's use is further predicated on unlawful commerce in violation of 21 C.F.R. §201.10(g)(1)[1] because Applicant has used the mark as a proprietary name for a prescription drug without providing the established name corresponding to such proprietary name each time it is feature on the label or in the labeling for the drug product. (OPP paragraph 8)

Registration of the mark LACTINOL by Applicant will likely harm Opposer because Applicant's use of a proprietary name without providing the established name for a prescription drug is likely to confuse Opposer's customers and the marketplace into believing that the drug or ingredient has some unique effectiveness or composition when, in fact, the drug is a common substance, the limitations of which would be readily recognized if Applicant disclosed the established drug or ingredient name. (OPP paragraph 9)

UNLAWFUL USE OF REGISTRATION SYMBOL PRIOR TO REGISTRATION

[1] *See also* 21 U.S.C. § 352(e).

Applicant's has otherwise violated the Trademark laws by accompanying the ® symbol in connection with the LACTINOL mark when no such registration has been granted by the United States Patent and Trademark Office or any other authority. (OPP paragraph 10)

Upon information and belief, Applicant used the ® symbol with the mark for the purpose of misrepresenting and falsely implying that Applicant's prescription lactic acid 10% drug products are FDA -approved branded items, and to divert sales from other sellers of prescription lactic acid 10% products, including Opposer, thereby causing injury to Opposer. (OPP paragraph 11)

Applicant's Present Partial Motion To Dismiss

On September 24, 2007, Applicant filed an Answer to the Notice of Opposition asserting various affirmative defenses and at the same time also filed the present "partial motion to dismiss" as against "paragraphs one (1) through ten (10) (sic)[2] of the Opposition". Applicant concedes Opposer's standing to challenge its unlawful use of the ®. Furthermore, Applicant does not contend that its product has FDA approval or that the label violations have been corrected. Applicant indicates that it is not moving to dismiss the remaining claim based on alleged misuse of the ® symbol and also states that "it [the unlawful use of the symbol] did not exist at the time Applicant filed its application". (See Applicant's Motion page 1.)[3] With regard to the paragraphs it does seek to dismiss, Applicant's motion fails to directly address any of the paragraphs of the Opposition as set forth above. Without challenging the specific allegations of damage, Applicant nevertheless asserts that with respect to the challenged claims, Opposer has not sufficiently pleaded its standing and that as regards the conceded requirement for FDA approval, Applicant argues that it ***may possibly*** be exempt from such requirement. Applicant's motion must be denied. Applicant does not dispute that it has failed to obtain the requisite FDA

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[2] Applicant apparently meant to refer to paragraphs 1-9.

[3] Applicant's misuse of the® symbol is described in paragraphs 10-11 of Rising's Opposition. Applicant appears to at least concede that it originally unlawfully used the ® symbol. The submitted specimen on file thus does not appear to correspond to the actual original use in 1992.

approval. Applicant also fails to dispute that its label violated the FFDCA at the time of application and appears to continue unabated. Particularly in light of *Creagri v. USANA Health Sciences, Inc.*, 474 F.3d 626, 630-34, 81 U.S.P.Q.2d 1592 (9th Cir. 2007), Opposer has set forth sufficient grounds to oppose the Application.

II: Standards

THE STANDARDS GOVERNING DETERMINATION OF A MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM UPON WHICH RELIEF MAY BE GRANTED

It is well established under federal practice and the TTAB Rules that a motion to dismiss for failure to state a claim is not directed to the resolution of disputed questions of fact. Its sole purpose is to test the legal sufficiency of the pleaded Opposition. Short and concise pleadings are favored. The Opposition need only allege such facts which, if proven, would establish the Opposer's standing in terms of the injury claimed and that there is a valid basis for denying the registration sought. The pleaded allegations are to be accepted as true and the pleading is to be sustained if any set of facts could be proven to support the claim. Finally, if some deficiency is found in the pleading, leave is to be liberally granted to amend the pleadings as may be required to correct the deficiency.

III: Discussion

The Opposition Sufficiently States A Claim For Relief

A. Regulatory Background and Applicant's Unlawful Use

The sale of prescription drug products is governed by the FDA under the FFDCA. Since 1938, the FFDCA has required drug manufacturers to obtain pre-approval by the FDA before they can lawfully market their new drugs. Under the FFDCA, all drugs are new drugs and therefore require an approved NDA or ANDA before marketing unless they are generally recognized among experts as safe and effective for their labeled use (the "GRASE" exception) or

are grandfathered. 21 U.S.C. § 321(p)(1); *Weinberger v. Hynson, Westcott & Dunning, Inc.*, 412 U.S. 609, 613 (1973).

Prior to 1962, in order for a drug manufacturer to obtain FDA approval, it merely had to file a New Drug Application ("NDA") or an Abbreviated New Drug Application ("ANDA") with the FDA and prove that the product was safe. In 1962, the FFDCA was amended to require proof that the product was effective as well as safe, which requirement was made retroactive to apply to all drugs that already had FDA approved NDAs based on safety. Manufacturers producing pre-1962 drugs were given a two-year window to submit revisions of their NDAs to prove their efficacy.

To facilitate the efficacy evaluations of these pre-1962 drugs, the FDA established the Drug Efficacy Study Implementation ("DESI") program. Under the DESI program, groups of drugs with approved NDAs were evaluated by an independent panel. If the panel found that the drugs met a certain standard for efficacy, the evidence was submitted to the FDA. If the FDA concurred with the DESI determination, a notice was published in the Federal Register and a supplemental NDA would be approved for these drugs. By its terms, the DESI program applied only to drugs that already had approved NDAs as of 1962. In conjunction with the DESI program, the FDA developed a policy whereby drugs that were identical, similar or related ("ISR drugs:) to an approved drug in the DESI review program could "piggy- back" off of the DESI review by submitting an ANDA after the DESI review established the efficacy of the pioneer drug. For a time, FDA policy allowed a drug manufacturer to market an ISR drug after filing, but before approval of an ISR drug's ANDA. This policy was challenged in court and overturned in 1975. *See Hoffman-LaRoche, Inc. v. Weinberger,* 425 F. Supp. 890, 894 (D.D.C. 1975)("[T]he Court holds that the FDA's policy of permitting new drugs to be marketed without

an approved new drug application contravenes the clear statutory requirement of preclearance mandated by 21 U.S.C. § 355."). In response to that decision, the FDA published a revision to its policy guidelines (Marketed Unapproved Drugs) that "clarified" the agency's position. CPG 7132c.02, which, reads in part:

> The agency has decided to *reaffirm* that all products marketed as drugs under the DESI program are new drugs, and therefore, require an approved NDA or ANDA for marketing. In view of the reaffirmation of this policy, the agency must proceed to remove from the market all current DESI-effective prescription products that are not subjects of approved NDA's or ANDA's, and to prevent in the future the marketing of such unapproved products. FDA Compliance Policy Guidelines § 440.100 (emphasis added).[4]

Instead of complying with the mandatory FDA approval process as set forth above, Applicant instead decided as early as 1992 to take advantage of the FDA's backlog in enforcement by marketing a prescription product Brand name 10% Lactic Acid product under the name LACTINOL. Applicant marketed LACTINOL without seeking FDA approval and by using a label which failed to disclose the established name of the product as required by law and with a false claim that Lactinol was a registered Trademark. Opposer, Rising Pharmaceuticals, believing at first that Pedinol's product was lawful, introduced a competing product sold under the generic name ("lactic acid 10%") and in compliance with the FFDCA label requirements, including conspicuously stating the established name as required under 21 U.S.C. § 352(e).

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[4] *Quoted in Florida Breckenridge, Inc. v. Solvay Pharmaceuticals, Inc.*, 174 F.3d 1227, 1229 (11th Cir. 1997), *withdrawn from publication.* The FDA's Compliance Policy Guideline document goes on to create priorities for the removal of unapproved drugs from the market. According to the FDA, there were so many unapproved drugs on the market that they needed to establish a triage system: "Considering the magnitude of the problem, the limitation on FDA's resources, and the resulting long time period before compliance can be fully attained, the agency has developed a strategy to handle unapproved products on a priority basis." The FDA has continued to reaffirm its position on such drugs and issued a supplemental Compliance Policy Guide in June 2006. *See http://www.fda.gov/cder/guidance/6911fnl.pdf*

The parties later became embroiled in a lawsuit pending in the United States District Court for the Eastern District of New York wherein issues partially similar to those raised here were ***recently found to raise questions of fact requiring a trial***. *See generally Pedinol Pharmacal, Inc. v. Rising Pharmaceuticals, Inc.*, ----F. Supp.2d ---, 2007 WL 2572124 (E.D.N.Y. Sept. 4, 2007). Indeed, in that very action, Opposer, *inter alia*, seeks to enjoin Pedinol from falsely claiming FDA approval or Registered Trademark status. In response, Pedinol filed the instant trademark application which was followed by the present Opposition proceeding.

B. Unlawful Use Cannot Give Rise To the Right to Registration

The issue raised by the present proceeding goes to the essence of the integrity of the Registration process. The United States Trademark Trial and Appeal Board has adopted a "lawful use in commerce" doctrine that inasmuch as trademark and Registration rights are dependent on the use in commerce, such rights can **only** by created or claimed when the use in commerce is lawful. *See Gray v. Daffy Dan's Bargaintown*, 823 F.2d 522, 526 3 U.S.P.Q.2d 1306, 1308 (Fed. Cir. 1987) ("A valid application cannot be filed at all for registration of a mark without `lawful use in commerce,'"...); *Carolina Exports Intern., Inc. v. Bulgari, S.p.A.*, 108 F.3d 1394 (Fed. Cir. 1997) (unpublished) (affirming TTAB's grant of Bulgari's motion for summary judgment on the ground of unlawful use due to the established fact that Applicant did not and would not comply with governmental regulations related to its intended use of the BULGARI mark); *In re Midwest Tennis & Track Co.*, 29 U.S.P.Q.2d. 1386, 1386 n.2 (T.T.A. B. 1993); *Clorox Co. v. Amour-Dial, Inc.*, 214 U.S.P.Q 850, 851 (T.T.A.B. 1982); *In re Pepcom Indus., Inc.*, 192 U.S.P.Q. 400, 401 (T.T.A.B. 1976); *In re Stellar Int'l, Inc.*, 159 U.S.P.Q. 48, 51 (T.T.A.B. 1968).

A party's use that is in violation of the FFDCA, including one for not complying with federal labeling regulations, cannot result in the grant of a federally registered trademark. *See, e.g., Creagri v. USANA Health Sciences, Inc.*, 474 F.3d 626, 630-34, 81 U.S.P.Q.2d 1592 (9th Cir. 2007); *Colorox Co.*, 214 U.S.P.Q. at 851 ("It has been the consistent position of this Board and the policy of the Patent and Trademark Office that a 'use in commerce' means a 'lawful use in commerce', and the shipment of goods in violation of [a] federal statute, including the Food, Drug and Cosmetic Act, may not be recognized as the basis for establishing trademark rights."); *Coahoma Chemical, Co. v. Smith,* 113 U.S.P.Q. 413 (Comr. 1957), *aff'd*, 264 F.2d 916, 121 U.S.P.Q. 215 (Cust. & Pat.App. 1959).

The reasons for the unlawful use in commerce bar rule have been explained by both the Board and the courts as being comprised of two parts. First, as a logical matter, the government should not be in the anomalous position of extending statutory benefits of trademark protection to a seller based upon use and commerce in violation of the government's own laws. Second, it would totally defeat the government's policy of securing voluntary compliance with the law to give trademark protection to a seller who rushes to the market before the government can take adequate action on the merits of its product and without the seller having made any inquiry of the government as to the compliance of his proposed course of action.

The above principles are both fully applicable in this case. At the same time as the FDA struggles to clear up the backlog in removal of unapproved products from the market place, Applicant has rushed to exploit that back log by marketing which is *per se* materially unlawful as an unapproved drug with a *per se* materially unlawful label which fails to disclose the established name of the product in conjunction with the proprietary name -- i.e. the very

trademark which Pedinol now seeks to register. The legal violation thus have a direct relationship to the trademark use. As noted by the *Creagri* court:

> [W]e should not refuse registration or order the cancellation of a registration because of some purely collateral defect such as the use of a container which did not comply with an ICC regulation or the failure of a party to pay an excise tax. ... [But, as] a general proposition, subject to qualification as the facts of particular cases require, I may venture to say that a registration *should* be refused or cancelled when it is unlawful to ship the goods in commerce (either because any shipment is forbidden or because required prior approval was not obtained) *or when the contents of the labeling [sic], of which the mark is a part, are unlawful."*

Creagri v. USANA Health Sciences, Inc., 474 F.3d at 631, 81 U.S.P.Q.2d 1592, *quoting Satinine Societa in Nome Collettivo v. P.A.B. Produits*, 209 U.S.P.Q. 958, 967 (T.T.A.B. 1981) (Kera, concurring) (emphasis added).

Applicant's assertion that the Opposition fails to state a claim is without merit under the applicable precedents. Applicant offers no explanation for its violation of the labeling requirement with regard to the placement of the established name on the principle display panel in conjunction with the claimed mark LACTINOL, a fact which directly injures Opposer who utilizes the established generic name. Applicants' lengthy attempt to otherwise set forth a number of hypotheticals which would establish potential exemption from the FDA approval requirement (but not labeling) is meritless. First, courts have rejected the very types of claims now being advanced by Pedinol. *E.g., Florida Breckenridge, Inc. v. Solvay Pharmaceuticals, Inc.*, 174 F.3d 1227, 1229 (11th Cir. 1997), *withdrawn from publication.* The Ninth Circuit in *Creagri* recently dealt with the very same type of argument and rejected it because CreAgri failed to show that it had applied to the FDA to confirm the exemption which it was supposedly entitled to. *CreAgri*, 474 F.3d at 632. Indeed, here FDA regulations provide the procedure for obtaining a ruling from the agency as to the supposed inapplicability of the approval process.

See 21 C.F.R. §314.200(e) ("Contentions that a drug product is not subject to the new drug requirements"). Applicant has not used this application process to establish the theoretical exemptions which it asserts might apply. Applicant therefore is not entitled to registration in light of the material and direct unlawful use in commerce upon which the Application is based.

Finally, Opposer respectfully submits that the issues raised by Applicant's motion are unsuitable for determination on the instant motion to dismiss. Essentially, Applicant is trying to parlay the affirmative defenses stated in its Answer as the basis for the present motion before Opposer has had the opportunity to show that the factual assertions made by Applicant are simply untrue. Opposer hereby advises the Board that discovery taken in the District Court action between the parties and which will be adduced in the Opposition proceedings shows that Applicant's claim of lawful activity are untrue. The evidence will show that internally Applicant fully recognizes that its product is unlawfully marketed and in fact Applicant has commenced various marketing options to deal with the expected FDA removal of its product from the marketplace. Opposer -- both by expert testimony and the aforementioned type of evidence -- is entitled to establish the alleged *per se* unlawful use as claimed in its Opposition. The motion to dismiss for failure to state a claim must therefore be denied.

C. Opposer has Sufficient Standing to Raise the Opposition

No basis is shown in Applicant's motion to question Opposer's standing as a competitor to proceed based upon the injury specifically pleaded in the opposition. Nor does Applicant contend that Opposer otherwise lacks standing to challenge Applicant's unlawful use of the ® symbol.

Furthermore, the Board has made clear that there is a liberalized standing requirement, designed to weed out mere intermeddler's which Opposer – as a direct competitor – is plainly not.

> Our reading of recent published case law of the Federal Circuit leads us to the inescapable conclusion that the requirements for standing have been liberalized. The standing question is an initial and basic inquiry made by the Board in every inter partes case; that is to say, standing is a threshold inquiry. This inquiry is directed solely to establishing the personal interest of the plaintiff. The continuing pronouncements of the Federal Circuit leave us with the understanding that there is a low threshold for a plaintiff to go from being a mere intermeddler to one with an interest in the proceeding. The Court has stated that an opposer need only show "a personal interest in the outcome of the case beyond that of the general public." **Once this threshold has been crossed, the opposer may rely on any ground that negates applicant's right to the registration sought**.

Estate of Biro v. Bic Corp., 18 U.S.P.Q.2d 1382, 1385-86 (T.T.A.B 1991), *citing Jewelers Vigilance Committee, Inc. Ullenberg Corp.*, 823 F.2d 490, 2 U.S.P.Q.2d 2021, 2023 (Fed. Cir. 1987); *Lipton Industries, Inc. v. Ralston Purina Co.*, 670 F.2d 1024, 1029-30, 213 U.S.P.Q. 185, 188 (CCPA 1982) (emphasis added).

More particularly, the test for standing is whether the Opposer has a reasonable belief that it will be damaged by the registration of the mark, and whether that belief reflects a real interest in the issue. *Ritchie v. Simpson*, 50 U.S.P.Q.2d 1023, 1027 (Fed. Cir. 1999). In *Ritchie*, the Federal Circuit found that the Opposer had standing based upon his belief that registration of the mark O.J. SIMPSON, among others, would disparage his values as a family man who believed in the sanctity of marriage, because the subject marks were synonymous with a wife-beater and wife-murderer.

Here, Opposer offers much more than a belief that it will be disparaged by registration of the subject mark. In fact, Opposer has alleged that it will be damaged if its competitor is permitted to register a mark based upon a use in commerce which is alleged to be unlawful. Opposer is not a mere intermeddler. *Ritchie*, 50 U.S.P.Q.2d at 1030-1031. Rather, Opposer has a

personal interest beyond that of the general public in that Opposer' is a competitor of Applicant, both parties manufacture a competitive generic lactic acid product, and Opposer has a reasonable belief that the alleged injuries will result if registration is granted. Applicant has not shown otherwise.

Further, by not moving to dismiss Opposer's claims premised on Applicant's unlawful use of the ® in connection with its purported LACTINOL mark when no such registration was granted by the USPTO or any other authority, Applicant impliedly concedes standing and Opposer is free to "rely on any ground that negates applicant's right to the registration sought." *Estate of Biro*, 18 U.S.P.Q.2d at 1385-86. Moreover, as a generic competitor, Applicant's failure to identify the established name together with the proprietary name as required under 21 U.S.C. § 352(e) and 21 C.F.R. §201.10(g)(1) harms Opposer because Applicant's product is made to appear as something more or different than Opposer's than it really is. *See* Opposition at ¶¶8-9. Opposer has also been directly injured by Applicant's failure to obtain FDA approval via an NDA because this has blocked Opposer's own ability to obtain an approval for an ANDA.

In any event, Applicant's standing argument misses the point. Opposer's standing is established by its showing of injury as pleaded. Once standing is obtained, Opposer has the right to raise all deficiencies in the Application without having to show separate standings to challenge each issue which should lead to rejection of the Application.

IV: CONCLUSION

For the reason set forth above applicant's motion to dismiss for failure to state a claim should be denied. In the alternative if the board feels that Rising's opposition pleading is deficient, Rising respectfully requests that leave be granted to amend the opposition in light of the ruling rendered.

October 29, 2007

Respectfully submitted,

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CERTIFICATE OF SERVICE

I, the undersigned, Michael Sarney, hereby certify that, on the 29th day of October, 2007, I caused to be served a true and correct copy of

MEMORANDUM OF LAW FOR RISING PHARMACEUTICALS, INC. IN OPPOSITION TO APPLICANT'S PARTIAL MOTION TO DISMISS FOR FAILURE TO STATE A CLAIM UPON WHICH RELIEF CAN BE GRANTED

by U.S. Mail, first class, by depositing the same in a depository of the United States Postal Service, on:

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